mum deliverable volume of 1.14 mL while providing a larger operating buffer for the vacuum stoppering setting and stopper placement requirement. The vacuum stoppering settings were kept between 70-75 mBar while the stopper dwell time was changed to 250 ms. When tested using WFI, this eliminated the problem of product suction into the vacuum chamber. The stoppering placement requirement (with the top of the stopper at least 3.0 mm below the distal side of the syringe flange) was, however, met on the stoppered syringes. A lower-than-desired stoppering consistency was achieved, but this was determined to be due to the clipped flanges of the syringes. To verify that the clipped flanges were the cause of the stoppering consistency, two tubs of 80 syringes each (160 syringes total) of round-flanged 1 mL-long syringes were used on the syringe filler. This resulted in a marked decrease in stoppering rejections, as compared to the stoppering rejections seen in the run with clipped-flange syringes.

[0084] The syringe filler set at a target fill volume of 1.19 mL was then used to fill syringes using WFI, the placebo, and the antibody A formulated substance. 160 syringes were filled with each of the five different fluids and at each of three different machine speeds (40%, 65%, and 90%) (with the exception of 87.7 mg/mL antibody A at 40% speed, for which only 35 syringes were filled, and 87.7 mg/mL antibody A at 65% speed, for which none were filled, due to an insufficient amount of product being available). All syringes were stoppered using a Hypak stoppering machine. Deliverable volumes from 20 filled and stoppered syringes from each batch were then measured. Deliverable volumes were measured by expelling volume from each of the 20 syringes, weighing the expelled volume, and converting the weight to volume using the following densities:

TABLE 5

Formulated Substance	Density
Placebo	1.023 g/mL
87.7 mg/mL antibody A	1.047 g/mL
131.6 mg/mL antibody A	1.059 g/mL
175 mg/mL antibody A	1.072 g/mL

[0085] Deliverable volumes were calculated to be as follows:

TABLE 6

Condition	Avg. Vol. (mL)	Max. Vol. (mL)	Min. Vol. (mL)
WFI - 40% speed	1.18	1.19	1.16
WFI - 65% speed	1.17	1.18	1.17
WFI - 90% speed	1.18	1.20	1.15
Placebo - 40% speed	1.18	1.19	1.18
Placebo - 65% speed	1.18	1.19	1.18
Placebo - 90% speed	1.19	1.22	1.18
87.7 mg/mL antibody A - 40% speed	1.17	1.19	1.15
87.7 mg/mL antibody A - 65% speed	N/A*	N/A*	N/A*
87.7 mg/mL antibody A - 90% speed	1.19	1.20	1.17
131.6 mg/mL antibody A - 40% speed	1.16	1.19	1.14
131.6 mg/mL antibody A - 65% speed	1.18	1.20	1.16
131.6 mg/mL antibody A - 90% speed	1.17	1.19	1.15
175 mg/mL antibody A - 40% speed	1.19	1.20	1.17
175 mg/mL antibody A - 65% speed	1.18	211.1	1.17
175 mg/mL antibody A - 90% speed	1.18	1.20	1.15

*Insufficient product was available to run this test.

[0086] Stoppering heights were measured from the top of the stopper to the distal side of the syringe flange, and were measured and calculated to be as follows:

TABLE 7

Condition	Avg. Stoppering Height (mm)	Max. Stoppering Height (mm)	Min. Stoppering Height (mm)
WFI - 40% speed	5.7	6.0	5.4
WFI - 65% speed	5.4	5.5	5.4
WFI - 90% speed	5.5	5.7	5.3
Placebo - 40% speed	5.4	5.5	5.4
Placebo - 65% speed	5.5	5.7	5.5
Placebo - 90% speed	5.8	6.0	5.5
87.7 mg/mL antibody A - 40% speed	5.5	5.8	5.4
87.7 mg/mL antibody A - 65% speed	N/A*	N/A*	N/A*
87.7 mg/mL antibody A - 90% speed	5.5	6.0	5.4
131.6 mg/mL antibody A - 40% speed	5.5	6.2	5.3
131.6 mg/mL antibody A - 65% speed	5.5	5.6	5.4
131.6 mg/mL antibody A - 90% speed	5.5	5.5	5.4
175 mg/mL antibody A - 40% speed	5.4	5.5	5.2
175 mg/mL antibody A - 65% speed	5.5	5.7	5.4
175 mg/mL antibody A - 90% speed	5.5	6.0	5.4

*Insufficient product was available to run this test.

Example 3

[0087] A plurality of PFS were overfilled by hand as follows. Three formulated substances (87.7 mg/mL antibody A, 131.6 mg/mL antibody A, 175 mg/mL antibody A) were prepared and frozen at −80° C. Each substance was removed from frozen storage and thawed for 16 hours. The substances were mixed, filtered, and transferred to 2-8° C. as follows:

TABLE 8

Formulated Substance	Mixing Time	pH	Filtration Time	Filtration Yield	Total time of exposure at room temp. after thawing
87.7 mg/mL antibody A	12 min	6.04	7 min	94%	100 min
131.6 mg/mL antibody A	12 min	6.11	11 min	93%	85 min
175 mg/mL antibody A	11 min	6.02	21 min	91%	60 min

[0088] The redundant filtration lines for 87.7 mg/mL antibody A and 131.6 mg/mL antibody A consisted of two Millipak 20s and ¼"×⅜" Pt cured silicone tubing for the product pathway. The redundant filtration lines for 175 mg/mL antibody A consisted of two Millipak 40s and ¼"×⅜" Pt cured silicone tubing for the product pathway. A peristaltic pump was used as the motive force for filtration.

[0089] The PFS filled in this procedure included 1 mL BD Hypak Physiolys SCF™ low tungsten syringes (Beckton Dickinson Medical), paired with 1 mL BD Hypak PS Flurotec plunger stoppers and 1 mL BD Hypak 21510 PR C Plunger Rods (Beckton Dickinson Medical). The desired placement of the top of the stopper was at least 3.0 mm below the distal side of the syringe flange. Filling in this procedure was completed by hand using a Watson-Marlow pump. Stoppering was completed using a Becton Dickson Hypak vacuum stoppering unit.